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Erectile dysfunction following pelvic fracture

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Erectile dysfunction following pelvic fracture

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2017

DECLARATION

I, Daou Abulkasem Gdeh, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the division of Urology, Department of Surgery of the University of the Witwatersrand, Johannesburg. It is also being submitted to the College of Medicine of South Africa in partial requirement for the qualification of Fellowship of the College of Urology.

Daou Gdeh: ……

On the ……day of ……., 2017

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List of abbreviations:

- ED: Erectile Dysfunction.
- CMJAH: Charlotte Maxeke Johannesburg Academic Hospital.
- HJH: Helen Joseph Hospital.
- CHBAH: Chris Hani Baragwanath Academic Hospital.
- MSDC: Male Sexual Dysfunction Clinic
- IIEF: the International Index of Erectile Function

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Abstract

Background:

Erectile dysfunction is one of the most important sequelae of pelvic fractures and may be transient or permanent. It can range from weak erections to severe sexual dysfunctions. Importantly, erectile dysfunction is more prevalent when the pelvic fracture is associated with urethral injury.

Methods:

- This was a retrospective study of patient records, with a prospective questionnaire arm for patients admitted to the hospitals with a pelvic fracture between 01/07/2011 to 30/04/2015.
- The electronic databases of the Orthopedic Department at Helen Joseph Hospital and the Male Sexual Dysfunction Clinic at Charlotte Maxeke Johannesburg Academic Hospital were accessed for patients' contact details, by using the name and hospital number of each patient.
- Each patient was contacted telephonically with an open speaker in a presence of a witness/translator. The information sheet was read to the patient before the telephonic consent was obtained.
- After consent was obtained, patients were asked to verbally complete the International Index of Erectile Function score questionnaire.

Results

A total of 53 patients participated in the study, of which (43.4%) reported erectile dysfunction. The majority of patients indicated a recovery of erectile function between 2

to 8 months after the injury. Most were found to still suffer from other forms of sexual impairment like orgasmic dysfunction and sexual satisfaction. However, sexual desire seemed to be preserved. Patients with sexual dysfunction were more likely to have had a urethral injury as well as a more severe fracture.

Conclusions

In our sample of 53 patients almost half reported sexual dysfunction after a pelvic fracture. Importantly, patients with urethral damage and a severe pelvic fracture should be followed up, as the risk of sexual dysfunction is high in these particular patients.

Chapter 1 - Introduction and review of the literature

1.1 Background

Pelvic fractures usually occur in older people, with osteoporosis, due falls and minor injuries, those types of pelvic fractures are usually not associated with urological complications including ED [1].

Pelvic fractures in young and healthy people are usually occur as a result of high energy trauma e.g. pedestrian vehicle accidents, motor vehicle accidents, crushing injuries or fall from heights [2].

There are several classifications of pelvic fractures, the most commonly used classification systems are:

1. Tile Pelvic Classification
2. Young and Burgess classification

The Tile Pelvic Classification was used in this study. It has 3 major groups (A, B and C), each of these groups is subdivided into 3 subtypes as following:

- A: Stable
    - A1: the fracture is not involving the pelvic ring (avulsion innominate bone, crest fracture or iliac wing fracture)
    - A2: stable or minimally displaced fracture of the pelvic ring
    - A3: transverse sacral fracture (Denis zone III sacral fracture).

- B: Rotationally unstable, vertically stable
    - B1: open book injury (external rotation)

- B2: lateral compression injury (internal rotation)
- B3: bilateral compression injury.

- C - Rotationally and vertically unstable
  - C1: unilateral
  - C2: bilateral
  - C3: bilateral and associated with acetabular fracture [1].

The other classification of pelvic fracture is Young and Burgess Classification of pelvic fractures [3], as follows:

Table 1.1: Young and Burgess Classification of pelvic fractures

Type	Description
1) Anterioposterior compression (APC)	
APC I	Diastasis of symphysis <2.5cm
APC II	Diastasis of symphysis >2.5cm, diastasis in the anterior part of the SI joint, while posterior SI ligaments are intact
APC III	Diastasis of symphysis >2.5cm, disruption of both anterior and posterior SI ligaments with dislocation in the SI joint
2) Lateral compression (LC)	
LC I	Oblique fracture of pubic Rami and anterior compression fracture of sacral ala on ipsilateral side
LC II	Fracture of pubic Rami and posterior fracture of ipsilateral iliac bone with dislocation
LC III	Ipsilateral lateral compression (LC) and contralateral anterioposterior compression (APC)
3) Vertical shear (VS)	
vs	Fracture by superior and posterior force

Pelvic fractures can result in long term urological complications, including urethral stricture (as a result of urethral injury), urinary incontinence and ED [4, 5]. Indeed,

urethral injury is seen in 4 – 25% of pelvic fracture cases. There is a strong relationship between pelvic fracture and subsequent sexual dysfunction, especially if the patient had an urethral injury too. Compared to the other causes of ED, pelvic (or perineal) trauma accounts for 3 - 5% of all ED cases [6].

It was believed that the early urethral repair can help to avoid ED [7, 8, 9, 10, 11, 12]. However, Subasi *et al*., (2004) studied 55 male patients who had severe pelvic fractures. Eleven (20%) of them had urethral injuries, and six (14.6%) of the 11 patients developed ED regardless of timing of urethroplasty (early or late) [4]. Furthermore, Barrett *et al*., (2013) compiled a systemic review and a meta-analysis, reviewing 161 articles on pelvic fractures accompanied by urethral injuries. They compared outcomes of those who had early urethral realignment to those who had late repair. Both groups showed ED [13].

The prostatic urethra is the most fixed portion of the human male urethra. It is fixed to the symphysis pubis and ischiopubic rami by puboprostatic ligaments and the urogenital diaphragm, making the prostatic urethra vulnerable to rupture by any shearing forces accompanying pelvic fracture [14, 15, 16]. Furthermore, any superior or posterior displacement of the symphysis pubis will also result in disruption of the prostatic urethra [6]. Patients will present with urethral bleeding, urinary retention and a high riding prostate on clinical examination. Urethral injury following a pelvic fracture most commonly occurs in the bulbomembranous part of the urethra [17].

Few studies have reported on the overall incidence of sexual dysfunction following pelvic trauma. In 2001 Machtens *et al.*, reported that in 1722 men who were involved in major trauma and who sustained pelvic fractures, 200 (11.6%) developed ED [18]. Malavaud *et al.*, (2000) reviewed 46 men who sustained pelvic fractures and recovered. However, all of them reported low sexual satisfaction. Indeed 11 (23.9%) patients had significant sexual dysfunction and impotence was seen in 19 (42%) of those who suffered urethral injuries [17]. King *et al.*, (1975) reported in a study done on 90 men who had pelvic fractures. Some of them had urethral injuries, of which 37 (42%) developed sexual dysfunction, while sexual impairment was seen in 4 (5.5%) [19]. In addition, Malavaud *et al.*, (2000) performed a study on 76 patients who had pelvic injuries. The International Index of Erectile Function (IIEF) score was used and 46 (60.5%) patients out of 76 patients responded to the questionnaire. Thirty seven (80.4%) of the 46 men reported that they had recovery of their sexual activity within 4 weeks, while the other 11 patients (29.7%) reported different degrees of sexual impairment [17].

Importantly, the etiology of erectile dysfunction following pelvic fracture can be due to vascular, neurological, corporal and/or psychological factors [19, 20, 21].

a) <u>Vascular</u>

Major pelvic trauma can result in major vascular damage because of the anatomy of the pelvis, which is rich in blood supply (to the pelvic organs and to the lower limbs). The vascular damage can be in the form of a vessel wall tear or intimal damage, of which either one can lead to vascular thrombosis and blockage [6, 22]. Indeed, Sharlip *et al*., (1981) reviewed the pelvic angiography of three patients, all of them revealed

obliteration of the internal pudendal artery at the level of the urogenital diaphragm. They remained sexually impaired despite good collateral vascular formation and good retrograde filling of the dorsal and deep penile vessels [23].

Another vascular cause of erectile dysfunction after pelvic injury is the formation of an arterio-venous fistula between the iliac vessels. Fortunately, ED in these cases can be reversed by surgical correction of the arterio-venous fistula [6].

b) Neurological

Severe pelvic neurological damage can also result in ED, especially if the damage involves the lumbosacral plexus. Neurological damage can occur at the time of injury or when the patient undergoes pelvic surgery. Some of these patients show partial neurological recovery within 3 - 24 months [6].

c) Corporal injury

Corporal injury in those who suffered pelvic trauma can also contribute to cause ED. The proximal part of the corpora is fixed to the surrounding structures and to the pubic rami, making it susceptible to shearing forces and hematoma formation. Healing of the hematoma by fibrosis around the corpora can occur, making it undilatable during sexual excitement [24].

d) Psychological

Psychological factors can also contribute and cause sexual dysfunction in patients who had severe trauma. One important factor is that those patients who survived major

trauma, usually stay in hospital for a long period of time, which predispose them to psychological problems such as depression, which can in turn affect their sexual activities [6]. Another factor to consider, is that up to 10% of people who survived a major traumatic injury can develop post-traumatic stress disorders [25]. Importantly, of those with post-traumatic stress disorder, 80% will develop sexual dysfunction [26]. Another compounding factor is that ED has been observed as a side effect of the medications used to treat post-traumatic stress disorder. However, sexual performance can be improved by the withdrawal of such medications [27]. Furthermore, any patient who has sexual impairment will develop a psychological response, which can ultimately worsen any underlying anatomical pathology [6].

1.2 Objectives

1) To evaluate the prevalence of ED post pelvic fractures in a South African sample population at Wits teaching hospitals (Charlotte Maxeke Johannesburg Academic Hospital “CMJAH”, Chris Hani Baragwanath Academic Hospital “CHBAH”, Helen Joseph Hospital “HJH”).

2) To determine the prevalence of spontaneous recovery of erectile function within the first 6 months from the time of injury.

Chapter 2 - Methodology

2.1 Study design

- This is a retrospective study of patient records from 01/07/2011 to 30/04/2015, with a prospective arm (Questionnaire).

2.2 Inclusion criteria

1. Patients who sustained type B or type C pelvic fractures (Tile Pelvic Classification).
2. Patients aged between 18 to 80 years

2.3 Exclusion criteria

1. Patients who had ED prior to the pelvic fracture injury
2. Patients suffering from other major medical- or psychological illnesses
3. Patients on medication that can affect erectile function
4. Patients who sustained head- or spinal injury
5. Patients who sustained major trauma and needed to stay three weeks or more in the ICU (intensive care unit)
6. Patients who used medications to treat ED within 4 weeks before answering the questionnaire

2.4 Timing of the study

The data collection took place between 01/11/2015 to 30/11/2015

2.5 Study location

HJH and the MSDC at CMJAH (unfortunately, the electronic databases at CHBAH and the trauma department at CMJAH were out of order and we could not access them)

2.6 Sample size

Fifty three participants.

2.7 Data collection

The database of the Orthopaedics Departments at HJH and the MSDC at CMJAH was accessed to obtain patient details. We accessed the electronic database of these two hospitals using the name and hospital number to obtain contact details of each patient. Each patient was contacted telephonically with an open speaker in the presence of a witness/translator. The information sheet was read to the patient before telephonic consent was obtained. Patients were then asked to verbally complete the International Index of Erectile Function (IIEF) score.

The orthopaedic database was also accessed to get patient demographic details and to classify them according to the severity of the pelvic fracture, using the Tile Pelvic Fracture Classification.

The results data were entered into an Excel spreadsheet for analysis.

2.8 Ethics

1. The project was approved by the Human Research Ethics Committee of the University of the Witwatersrand (Medical) (The ethics certificate was obtained on 28/08/2015 with the clearance number: **M150502**).
2. The ethics clearance certificate obtained is included as appendix IV.
3. The patient information sheet and the patient consent form are also included (Appendices II and III respectively).
4. All the patients personal details were only made available to myself for the purpose of this research study.
5. Patient confidentiality was respected by collecting the data anonomously and by using a numbering system on my data collection sheet without any personal identifiers such as names, surnames or birthdates.

2.9 Data analysis

Descriptive statistics using mean and standard deviation or median and range, as appropriate were used for analysis of numerical data. Categorical data were described using percentages. For the comparison of those patients with sexual dysfunction to those without, a combination of unpaired t-tests and Fishers Exact tests were used for numerical and categorical data respectively.

Chapter 3 – Results

A total of (53) participants answered the IIEF score questionnaire.

The orthopaedic database was accessed to obtain contact details and to classify the patients according to the severity of the pelvic fracture, using the Tile Pelvic Fracture Classification. Half (50.9%) of the patients had a B2 type of fracture and (20%) had a type C facture.

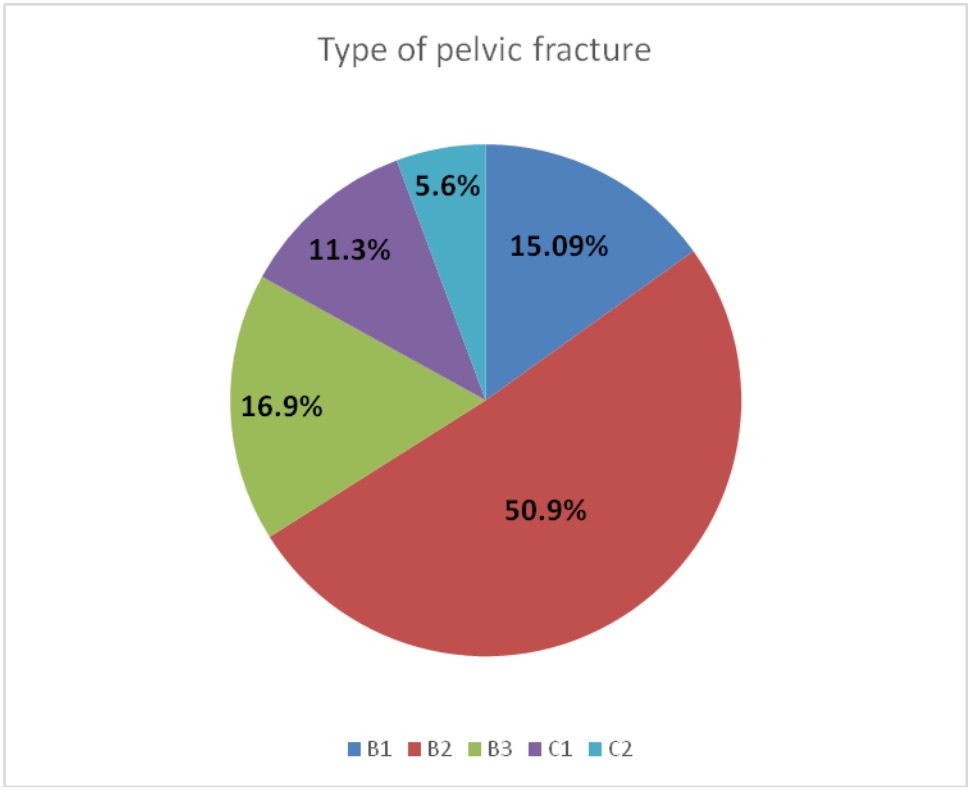

Fig 3.1: Distribution of participants according to the Tile Pelvic Classification

After analyzing the data, (43.4%) of the patients suffered ED secondary to the traumatic pelvic fractures.

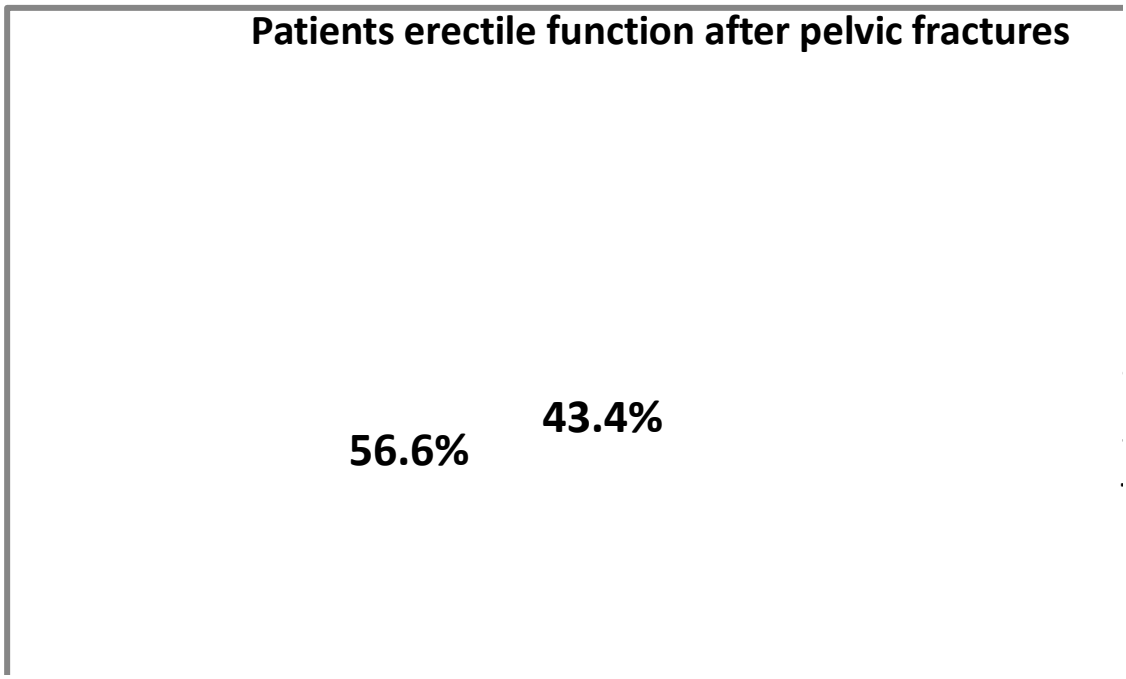

Fig 3.2: Prevalence of erectile dysfunction after pelvic fracture

Assessment of sexual dysfunction in those patients who reported sexual dysfunction (n=43) which is comparable to other international studies (discussed later in Chapter 4).

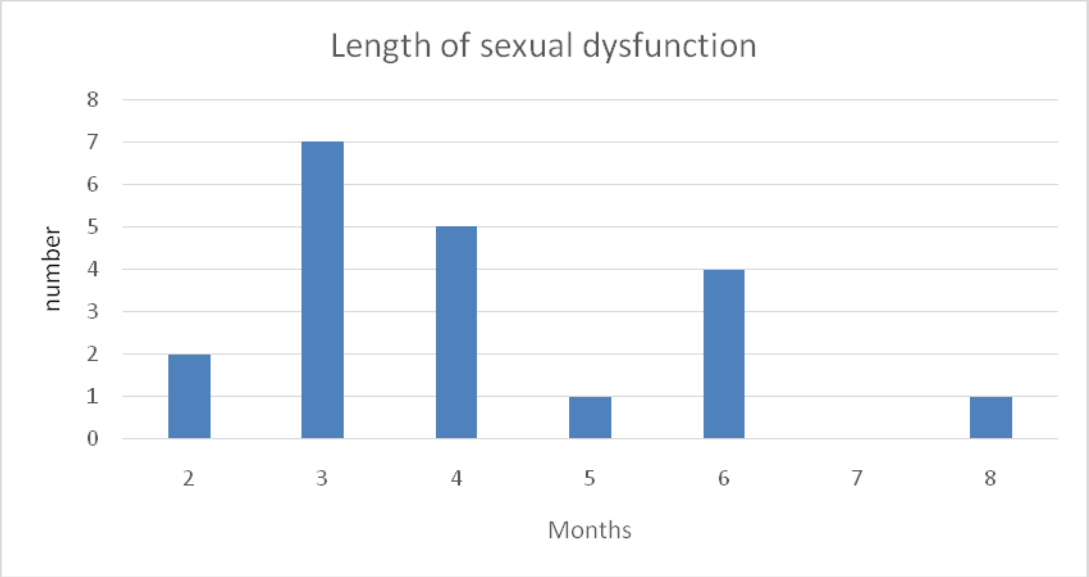

Fig 3.3: Spontaneous recovery period of erectile dysfunction post pelvic fractures

Most patients reported that by the time of assessment, their sexual dysfunction had resolved.

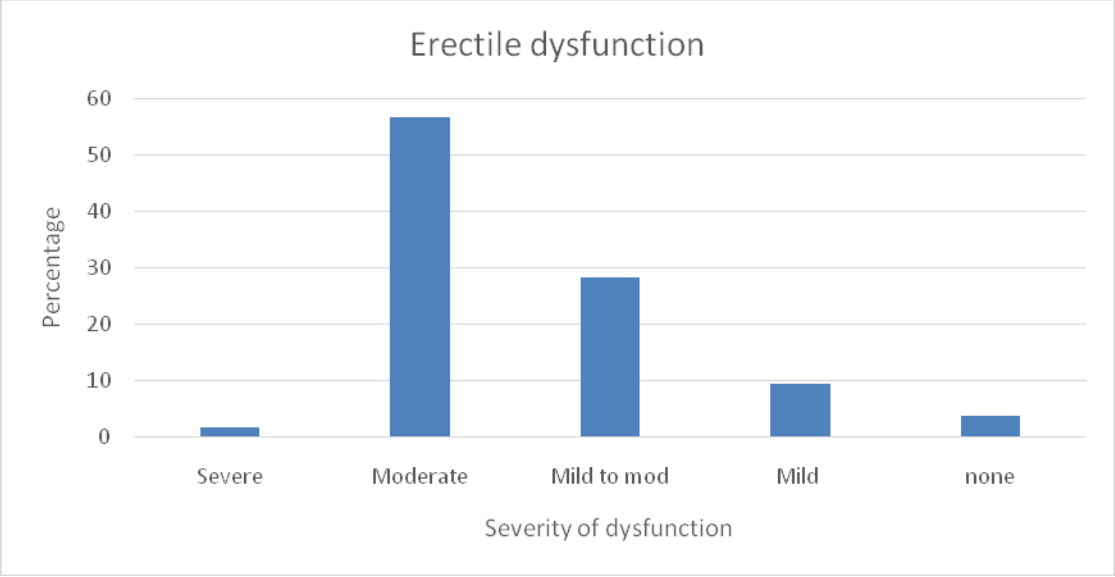

Fig 3.4: Severity of sexual dysfunction

Therefore, the majority (86%) of patients who developed ED after a pelvic fracture had mild to moderate sexual impairment, which can be in the form of orgasmic dysfunction, impaired sexual satisfaction or affected sexual desire.

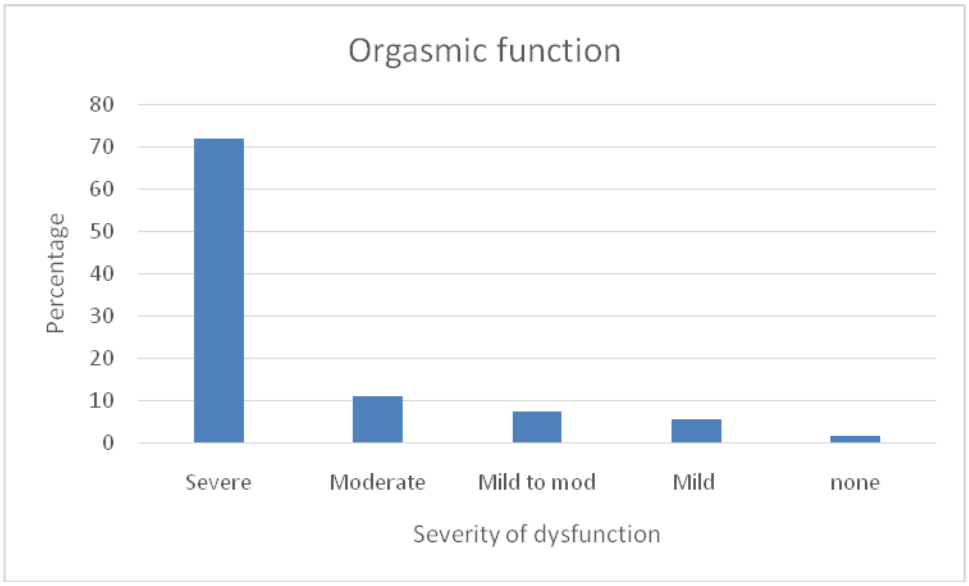

Fig 3.5: The prevalence of orgasmic dysfunction

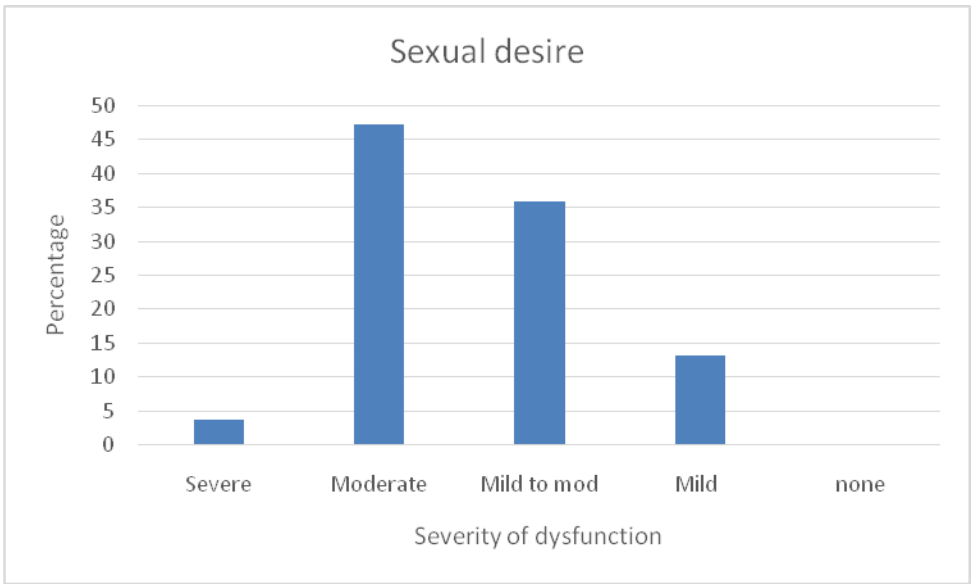

Fig 3.6: The prevalence of sexual desire impairment

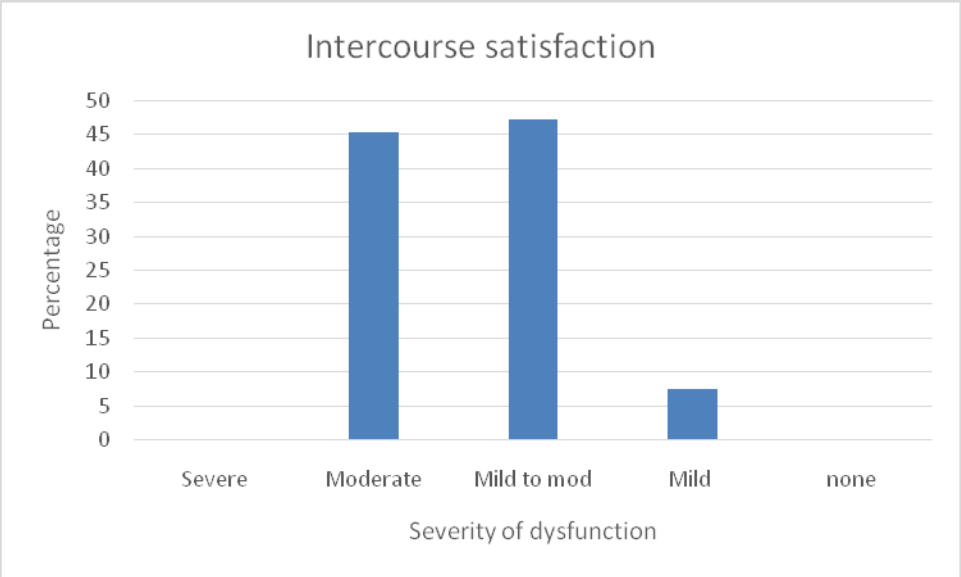

Fig 3.7: The prevalence of intercourse dissatisfaction

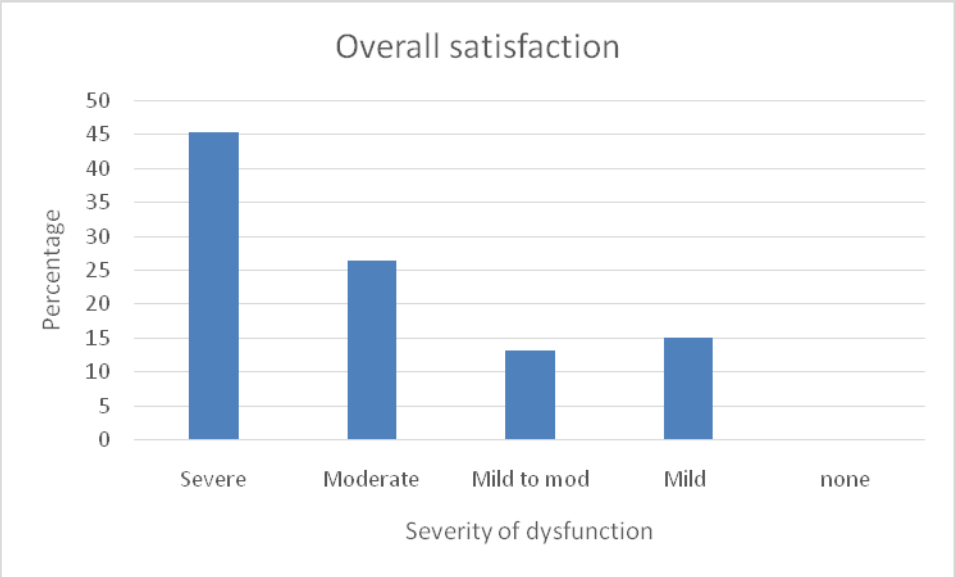

Fig 3.8: The overall sexual satisfaction impairment

Table 3.1: Statistical analysis of patients with and without sexual dysfunction

	No dysfunction	Dysfunction	P value	Test
n	30	23		
Age (years)	34.8 (14.3)	38.6 (13.2)	0.3317	Unpaired t-test
Time since injury (months)	28.9 (14.4)	24.9 (10.8)	0.2963	Unpaired t-test
Urethral injury (n/y)	28/2	9/12	0.0001	Fishers exact
Type B *vs* C*	29/1	15/6	0.0151	Fishers exact
Erectile dysfunction (median range)	10.5(8-19)	14(6-27)	0.0001	Fishers exact
Orgasmic dysfunction	2(2-8)	2(2-9)	0.0368	Fishers exact
Sexual drive	4(3-7)	5(2-8)	0.2558	Fishers exact
Intercourse satisfaction	6(4-10)	8(5-11)	0.0002	Fishers exact
Overall	2(2-7)	5(2-8)	0.001	Fishers exact

* Type B or C pelvic fracture as per Tile Pelvic Classification

There were no significant differences in age, time since injury or sexual drive between the two groups analysed. Patients with sexual dysfunction were significantly more likely to have urethral injury and type C pelvic fractures. Patients with sexual dysfunction scored significantly lower (indicating more disease) on all subsections of the sexual dysfunction questionnaire (except for sexual drive) as well as had a lower overall score.

Chapter 4 - Discussion

4.1 Discussion

There is a paucity in the literature on studies done to assess the rate of ED after pelvic fractures. None of these studies were done in South Africa. The overall rate of ED in the studies to be described below, ranged from 11 - 42%.

A number of pelvic classification systems exist. The most commonly used systems though, are the Tile Pelvic Classification and the Young and Burgess Classification. [1] In the present study, the Tile Pelvic Classification was used to classify the pelvic fractures of participating patients. The majority (n = 27or 50.9%) of the participating patients had Tile B2 fractures. For the other 26 patients, 8 had B1 (15%), 9 had B3 (16.9%), 6 had C1 (11.3%) and 3 had C2 (5.6%) type pelvic fractures.

Four out of 53 (7.5%) participants had hypertension (well controlled) and 8 patients (16%) were smokers, all of these had normal erectile function. However, 23 patients (43.3%) developed ED secondary to their pelvic fractures.

King *et al*., (1975), performed a study on 90 patients and found that 42% of patients developed ED, [19] whereas Malavaud *et al*., (2000), reviewed 46 patients who sustained pelvic fractures and 23.9% had ED [17]. Furthermore, Machtens *et al.*, (2001), reported in a much larger study, that out of 1722 participants, 200 (11.6%) suffered ED [18]. However, Malavaud *et al.,* (2000) reported in his study that 29.7% of the pelvic fracture patients developed a permanent sexual dysfunction [17].

Although the majority (86%) of the patients in our study reported recovery of their erectile function within 2 to 8 months, by looking into the other domains of the IIEF (orgasmic function, libido, sexual satisfaction and overall satisfaction) except for sexual desire, according to patients' answers, these aspects were lower, than in those patients who had no sexual dysfunction after the fracture. Indeed, out of the patients who reported recovery of erectile function, 72% still had severe orgasmic dysfunction, 80% had mild to moderate sexual desire (libido) impairment, 92% had mild to moderate intercourse dissatisfaction and 70% had moderate to severe overall dissatisfaction. King *et al.,* (1975), found in his study that 37 patients (42%) who developed ED, only 4 (5.5%) had permanent sexual dysfunction [19], but unfortunately they did not specify which aspect of sexual function was affected.

In contrast, Malavaud *et al.*, (2000), reported that a percentage as high as 80.4% of the patients in their study, showed a spontaneous sexual function recovery within 4 weeks [17]. In agreement, indeed, in our study, 86% of pelvic fracture patients reported recovery of their sexual functions and they were able to perform sexual intercourse to some extent. In most of these participating patients, their erections were recovered within 3 months and up to 8 months post injury.

However, most of these patients were not completely satisfied, and therefore, we reviewed the other domains of the sexual function (as mentioned above), and we noticed that they have impairment in one or more domains, as compared to those who have not developed ED after pelvic fracture, possibly for reasons such as chronic skeletal pain, painful ejaculation or urethral stricture (some of them they may still have a

stricture as a sequalae of the pelvic fracture and some had a failed urethroplasty and are awaiting repeat procedures).

Spontaneous recovery could be explained by recovery of neuropraxia, the absorption of a pelvic hematoma that was compressing on the neurovascular bundle that can result in pain resolving and improved mobility, or by other unknown reasons. Further studies will need to be done on this topic in the future.

4.2 Study limitations

- The lack of a functioning electronic database in the department of orthopaedics. Therefore, the principal investigator experienced difficulty in reading some handwriting.
- Some patients did not have contact details and some had changed their contact details and we could not get in touch with them.
- Limited data in the literature about this condition.

4.3 Conclusions

There were no significant differences between the two groups regarding age, time since injury or sexual drive. Patients with sexual dysfunction were significantly more likely to have urethral injury and type C pelvic fractures. Patients with sexual dysfunction scored significantly lower (indicating more disease) on all subsections of the sexual dysfunction questionnaire (except sexual drive) as well as on the overall sexual function score.

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Appendices

Appendix I:



CHARLOTTE MAXEKE JOHANNESBURG ACADAMIC HOSPITAL
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
DEPRTMENT OF UROLOGY

Study title: Erectile dysfunction following pelvic fracture

DATA COLLECTION SHEET

1) Participant information

- Participant study number :
- Age:
- Race :
- African White Asian Coloured Other
- Date of injury
- Associated urethral injury : Yes / No
- Type of pelvic fracture:
- Chronic medical illnesses : Yes / No (if yes please specify)
- Smoking : Yes / No

2) IIEF Questionnaire Assessment

If you are sexually active and/or desire evaluation, please continue with the questions below (Circle one answer for each question)

1. Over the past 4 weeks, how often were you able to get an erection during sexual activity?

0 No sexual activity

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

2. Over the past 4 weeks, when you had erections with sexual stimulation, how often were your erections hard enough for penetration?

0 No sexual stimulation

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

The next question is only applicable to patients who show normal score:

Have you had sexual difficulties in the first six months after your injury? Yes / No

If yes, for how long? Please circle

1 month 2 months 3 months 4 months 5 months 6 months

Questions 3, 4 and 5 will ask about erections you may have had during sexual intercourse.

3. Over the past 4 weeks, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?

0 Did not attempt intercourse

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

4. Over the past 4 weeks, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

0 Did not attempt intercourse

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

5. Over the past 4 weeks, during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

1 Did not attempt intercourse

2 Almost always or always

3 Most times (much more than half the time)

4 Sometimes (about half the time) 0 A few times (much less than half the time)

5 Almost never or never

6. Over the past 4 weeks, how many times have you attempted sexual intercourse?

0 No attempts

1 1-2 attempts

2 3-4 attempts

3 5-6 attempts

4 7-10 attempts

5 11 or more attempts

7. Over the past 4 weeks, when you attempted sexual intercourse how often was it satisfactory for you?

0 Did not attempt intercourse

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

8. Over the past 4 weeks, how much have you enjoyed sexual intercourse

0 No intercourse

1 Very highly enjoyable

2 Highly enjoyable

3 Fairly enjoyable

4 Not very enjoyable

5 Not enjoyable

9. Over the past 4 weeks, when you had sexual stimulation or intercourse how often did you ejaculate?

0 Did not attempt intercourse

1 Almost always or always

2 Most times (more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

10. Over the past 4 weeks, when you had sexual stimulation or intercourse how often did you have the feeling of orgasm or climax (with or without ejaculation)?

0 No sexual stimulation or intercourse

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never

Questions 11 and 12 ask about sexual desire. Let's define sexual desire as a feeling that may include wanting to have a sexual experience (for example, masturbation or intercourse), thinking about having sex or feeling frustrated due to a lack of sex.

11. Over the past 4 weeks, how often have you felt sexual desire?

1 Almost always or always

2 Most times (much more than half the time)

3 Sometimes (about half the time)

4 A few times (much less than half the time)

5 Almost never or never.

12 Over the past 4 weeks, how would you rate your level of sexual desire?

1 Very high

2 High

3 Moderate

4 Low

5 Very low or none at all

13. Over the past 4 weeks, how satisfied have you been with you overall sex life?

1 Very satisfied

2 Moderately satisfied

3 About equally satisfied and dissatisfied

4 Moderately dissatisfied

5 Very dissatisfied

14. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

1 Very satisfied

2 Moderately satisfied

3 About equally satisfied and dissatisfied

4 Moderately dissatisfied

5 Very dissatisfied

15. Over the past 4 weeks, how do you rate your confidence that you can get and keep your erection?

1 Very high

2 High

3 Moderate

4 Low

5 Very low

Domain Questions # Total Score

Erectile Function 1, 2, 3, 4, 5, 15 _____

Orgasmic Function 9, 10 _____

Sexual Desire 11, 12 _____

Intercourse Satisfaction 6, 7, 8 _____

Overall Satisfaction 13, 14 _____

Clinical Interpretation

I. Erectile function total scores can be interpreted as follows:

Score Interpretation

0-6 Severe dysfunction

7-12 Moderate dysfunction

13-18 Mild to moderate dysfunction

19-24 Mild dysfunction

25-30 No dysfunction

II. Orgasmic function total scores can be interpreted as follows:

Score Interpretation

0-2 Severe dysfunction

3-4 Moderate dysfunction

5-6 Mild to moderate dysfunction

7-8 Mild dysfunction

9-10 No dysfunction

III. Sexual desire total scores can be interpreted as follows:

Score Interpretation

0-2 Severe dysfunction

3-4 Moderate dysfunction

5-6 Mild to moderate dysfunction

7-8 Mild dysfunction

9-10 No dysfunction

IV. Intercourse satisfaction total scores can be interpreted as follows:

Score Interpretation

0-3 Severe dysfunction

4-6 Moderate dysfunction

7-9 Mild to moderate dysfunction

10-12 Mild dysfunction

13-15 No dysfunction

V. Overall satisfaction total scores can be interpreted as follows:

Score Interpretation

0-2 Severe dysfunction

3-4 Moderate dysfunction

5-6 Mild to moderate dysfunction

7-8 Mild dysfunction

9-10 No dysfunction

The next question is only applicable to patients who show normal score:

Have you had sexual difficulties in the first six months after your injury? Yes / No

If yes, for how long? Please circle

1 month 2 months 3 months 4 months 5 months 6 months

Appendix II:

CHARLOTTE MAXEKE JOHANNESBURG ACADAMIC HOSPITAL
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
DEPRTMENT OF UROLOGY

Study participant information sheet

Study title: Erectile dysfunction following pelvic fracture

Dear Mr

Good day, I am Dr Daou Gdeh, a registrar in the department of Urology at *Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)*, University of the Witwatersrand.
I am doing research on erectile dysfunction on people who exposed to fracture of the pelvis, so I will ask you to answer some questions on a sheet of paper, it will take only few minutes from your time, you do not have to write your name and I am not going to use your details in the entire study.
This research will give us lots of information about the condition, we possibly can find better solutions in the future studies, that can help maintain the sexual function after sustaining major accidents.
So your collaboration is very important to improve our care, and we can avoid permanent sexual disabilities in future.

Benefits of being in the study: If you suffer from sexual difficulty then I can refer you and arrange an appointment for you to be seen in Male sexual dysfunction clinic (Men's Clinic) at *Charlotte Maxeke Johannesburg Academic Hospital.*

Participation is voluntary: Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

You will not be paid money or remuneration of any sort as no extra costs will be incurred by you.

Confidentiality: As explained above you don't have to write your name on the answer sheet, we not going to use your details at all. Data from the study will be pooled, analyzed and may be presented at scientific meetings and medical journals. At no stage will it be possible to identify you as a participant of the study. You will be identified by a code number in the study data or in any publications produced from this study. You will be informed of any finding of importance to your health at your next clinic visit.

Contact details of researcher

If you have any question any time, please contact me at *CMJAH Ward 386, on 011 488 3386/3383. If you need to contact me about the study, please do not hesitate to phone me on 0734620573 or email me at daougdeh@gmail.com*

Appendix III:

CHARLOTTE MAXEKE JOHANNESBURG ACADAMIC HOSPITAL
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
DEPRTMENT OF UROLOGY

Study title: Erectile dysfunction following pelvic fracture
Participant Consent Form

Good Day Mr
I am Dr Daou Gdeh, from the urology department at Charlotte Maxeke Johannesburg Academic Hospital
I am conducting a study about erectile dysfunction following pelvic fractures. According to our records you were involved in a major accident and suffered a pelvic fracture, so I would like to ask you fifteen questions about your sexual function, it will take about ten minutes from you respected time.
Your cooperation is very important to us, it helps us understand the nature of the disease and we can plan further studies that possibly can find a solution that can help with sexual function
You have a chance to ask any question and I will answer it to your satisfaction.
If you do not wish to answer any particular question then it is okay.
Remember taking part in this study is voluntary and you give the permission for the use and sharing of your health related data. Your personal details will not appear in any part of this study.
No one will be able to identify you except the study doctor through your study code.
You may choose not to be in the study or to leave the study at any given time by informing the study *doctor and* you *will not be penalized or lose any benefits to which you otherwise entitled.*
Dr D Gdeh has informed me about the procedure of the study and I understand it well, and I give Dr D Gdeh the permission to use my health related informations.
PARTICIPANT

_____ _____
Print Name Date and Time

I, Dr Daou Gdeh, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study and that I have explained the participants right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.
STUDY DOCTOR

_____ _____
_____
Print Name Signature
Date and Time
WITNESS/TRANSLATOR
Print Name Signature
Date and Time

AppendixIV:

R14/49 Dr Daou Gdeh

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150502

NAME: (Principal Investigator)	Dr Daou Gdeh
DEPARTMENT:	Urology Charlotte Maxeke Johannesburg Academic Hospital Chris Hani Baragwanath HospitalHelen Joseph Hospital
PROJECT TITLE:	Erectile Dysfunction Following Pelvic Fracture
DATE CONSIDERED:	29 May 2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Mohamed Haffejee
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	28/08/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

AppendixV:

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

19 May 2015
Person No: 512015
PAG

Dr D Gdeh
17 Brookcliff Heights
20 De Wet Street
Northcliff Exr 3
Northcliff
2195
South Africa

Dear Dr Gdeh

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Erectile dysfunction following pelvic fracture* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences